DEC 2 0 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safety Medical Device Act of 1990 and 21 CFR Part 807.92

510(k) Number: K023408

Date of Summary Preparation:
October 5, 2002

Submitter:	Applied Biotech, Inc.
Contact Person:	Vivianne Noetzel
Phone:	858-756-8483
FAX:	858-759-7492
Address:	P.O. Box 9433 17394 Via Del Bravo Rancho Santa Fe, California 92067
Manufacturing Site:	Applied Biotech, Inc. 10237 Flanders Court San Diego, California 92121
Phone:	858-587-6771
Establishment Number:	2028231

Device Trade Name:	InstaCheck® Menopause Predictor Test
Device Common Name:	Follicle Stimulating Hormone Test
Device Classification:	Class 1 (21 CFR 862.1300)
Device Product Code:	CGJ
Performance Standards:	None established (as a medical device) under Section 514.
Device Description:	One step immunoassay for the detection of FSH in urine.
Intended Use	The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of FSH in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.
Indication for Use	The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of FSH in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

Substantial Equivalence Claim to:

SURESTEP FSH Menopause Test	K010556
Genua Menopause Monitor Test Kit	K002450

Summary of Device Consumer Testing:
STUDY CONCLUSION

The consumer study demonstrated that when the InstaCheck® Menopause Predictor Test was performed by a general public consumer population of diverse age, sex and educational background, there was an overwhelming favorable assessment of the package insert, with respect to readability (98.5%) and comprehension (99.6%).

The consumer study demonstrated that the consumer could complete the test 100% of the time. The consumer study also demonstrated that the consumer could perform the test with excellent accuracy (>99%).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 0 2002

Applied BioTech, Inc.
c/o Ms. Vivianne Noetzel
Noetzel Terratech
P.O. Box 9433
Rancho Santa Fe, CA 92067

Re: k023408
Trade/Device Name: InstaCheck® Menopause Predictor Test
Regulation Number: 21 CFR 862.1300
Regulation Name: Follicle-stimulating hormone test system
Regulatory Class: Class I
Product Code: CGJ
Dated: October 5, 2002
Received: October 10, 2002

Dear Ms.Noetzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K023408

Device Name: InstaCheck® Menopause Predictor Test

Intended Use The InstaCheck® Menopause Predictor Test is an *in vitro* diagnostic screen for the detection of human Follicle Stimulating Hormone, FSH, in urine. Changes in FSH levels in human urine are related to the symptoms associated with stages of menopause. The InstaCheck® Menopause Predictor Test is used to obtain a visual, qualitative result and is intended for over-the-counter sale to laypersons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023408

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓